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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,030	11/25/2003	Marcus Pfister	P03,0472	6512

26574 7590 08/04/2009

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ART UNIT	**PAPER NUMBER**
3737	

MAIL DATE	DELIVERY MODE
08/04/2009	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/722,030
Filing Date: November 25, 2003
Appellant(s): PFISTER ET AL.

Steven A. Noll
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/13/2009 appealing from the Office action mailed 8/15/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Application Serial No. 10/792,570 filed March 3, 2004 which is on appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the Examiner. Claims 1-13 as rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has

been withdrawn by the Examiner as the applicant concedes that modeling of the tissue is well known to one of ordinary skill in the art.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,999,836	Nelson et al.	12-1999

Sholz, Bernard. "Towards Virtual Electrical Breast Biopsy: Space-Frequency MUSIC for Trans-Admittance Data" IEEE Trans. Med. Imag., Vol. 21, No. 6 (June 2002), pp. 588-595.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

Claims 1-13 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (US 5,999,836) in view of Sholz ("Towards Virtual Electrical Breast Biopsy: Space-Frequency MUSIC for Trans-Admittance Data", IEEE Trans. Med. Imag., Vol. 21, No. 6, pp. 588-595).

The device of Nelson et al. discloses the method steps to spatially localize a region in a biological tissue section (abstract and col. 8, ln. 18-20) that, at least during an examination, exhibits a fluorescence property different from the tissue section (the properties are modified by the tissue through which the beam passes, column 18, lines 9-14), due to which, given an exposure with light of a first wavelength (claim 21 step 3),

light of another wavelength is emitted (claim 21 step 6), comprising the steps of: applying a sequence of fluorescence-exciting light signals at different locations on the tissue-section (claim 21, step 3), generating the fluorescence-exciting light signals with various modulation frequencies and radiating the light signals into the tissue section (column 15, lines 58-66), measuring fluorescence light arising due to the light signals, at a plurality of measurement locations on a surface of the tissue section, and thereby obtaining response signals (claim 21 step 6), determining frequency-independent signal portions (column 18, lines 9-12) in the response signals and further processing the frequency-independent signal portions (coherence, amplitude, spatial distribution, phase, etc.; column 18, lines 9-12) into input values for localization (claim 21 step 7), marking the regions with fluorescing markers to generate the various fluorescence properties (column 9, lines 65-67 through column 10, lines 1-4), and radiating the fluorescence- exciting light signals as laser light of suitable wavelength (column 15, lines 58-60). Nelson et al. also discloses a device for spatially localizing a region in a biological tissue section (abstract and col. 8, ln. 18-20) that at least during an examination, exhibits a fluorescence property different from the tissue section (column 18, lines 9-14), said device comprising an arrangement of light sensors 110 distributed on a surface of the tissue section (it would be obvious to one of ordinary skill in the art to move the sensors such that the sensors would be in contact with the surface of the tissue, column 14, lines 3-5 and figures 1b, 2b, and 2c), a laser diode arrangement 112 that emits fluorescence-exciting light that interacts with a fluorescing marked region in the tissue section (column 9, lines 65-67 through column 10, lines 1-4), causing the

marked region to emit fluorescence-exited light that is detected by the light sensors 110 in a two-dimensional measurement value distribution, said light sensors 110 generating response signals corresponding to said two-dimensional measurement value distribution (images are produced by the response signals, column 15, lines 57-63), and a processor (response signals are analyzed by a computer, column 5, lines 62-65) supplied with said response signals, said processor being configured to determine frequency-independent signal portions (column 18, lines 9-12) in the response signals and to further process the frequency-independent signal portions (column 18, lines 9-12) into input values for localization (column 5, lines 62-65), the arrangement of light sensors 110 comprises a first set of light sensors 110 and a second set of light sensors 110 adapted to be respectively disposed on opposite sides of said tissue section (column 14 lines 66-67 through column 15, lines 1-3, and figure 12), comprising an x-ray mammography apparatus having two compression plates 102, and wherein said light sensor arrangement 110 is Integrated into at least one of said compression plates 102 (figure 1b), the arrangement of light sensors 110 comprises a curved mounting 118 for said light sensors (contoured compression plates 118, figure 13a and 13b). Nelson et al. also discloses the arrangement of light sensors 110 comprises a flexible mounting (column 21, lines 58-60 and 65-67, and figure 20).

The patent of Nelson et al. does not teach the method steps of modeling the tissue section and determining a set of guide fields from the model, and transforming the guide fields and comparing the input values processed from the frequency-independent signal portions with the transformed guide fields, and emitting a three

dimensional location of the transformed guide fields that best reproduces the frequency-independent signal portions as a three dimensional location of the region to be localized, normalizing said guide fields, transforming the guide fields into orthogonal guide fields, determining the orthogonal guide fields from the guide fields by a singular-value decomposition, and determining optical parameters with reference measurements in non-fluorescence-exciting wavelengths by estimation. Nelson et al. also does not teach a processor for modeling the tissue section and determining a set of guide fields from the model, transforming the guide fields and comparing the input values processed from the frequency-independent signal portions with the transformed guide fields, and emitting a three dimensional location of the transformed guide fields that best reproduces the frequency-independent signal portions as a three dimensional location of the region to be localized.

However, the publication to Scholz teaches the method steps of modeling the tissue section and determining a set of lead fields from the model (abstract), and transforming the lead fields (section B last paragraph), emitting a three dimensional location (abstract, line 4) of the transformed lead fields that best reproduces the frequency-independent signal portions as a three dimensional location (abstract, line 4) of the region to be localized (section C), normalizing said lead fields (section C paragraph 2), transforming the lead fields into orthogonal lead fields (section C paragraph 2), and determining the orthogonal lead fields from the lead fields by a singular-value decomposition (section B). Nelson et al. discloses a dual modality system (optical and ultrasound; col. 20, lines 3-7) in which the use of a second modality

(col. 20, lines 3-7) aids in the identification of static and dynamic structures and in the identification of material composition of the structures (col. 20, line 65 to col. 21, line 1). Furthermore, Nelson et al. discloses that electromagnetic properties of various normal and diseased breast tissues exhibit wavelength dependence and examining the effects of tissue on other electromagnetic parameters may aid in distinguishing between various types of tissues (Nelson et al., column 7, lines 21-27), therefore one of ordinary skill in the art would recognize that by comparing the results from the device of Nelson et al. and Scholz, breast cancer localization can be enhanced. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide the method of tissue localization by Scholz to the device of Nelson et al. to improve breast cancer diagnosis (Scholz, abstract, lines 1-2). The modified device of Nelson et al. in view of Scholz would then render obvious the method steps of comparing the frequency-independent signal portions with the lead fields, emitting a location of the transformed lead fields that best reproduces the frequency-independent signal portions, and determining optical parameters with reference measurements in non-fluorescence-exciting wavelengths.

(10) Response to Argument

Applicant argued Nelson et al. does not teach "to spatially localize a region in a biological tissue section". However, the Examiner respectfully disagreed with the applicant. The recitation “to spatially localize a region in a biological tissue section” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the

purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Furthermore, applicant's arguments regarding the recitation have been previously addressed by the Examiner in the Final Office Action dated 2/13/08 in which the Examiner stated:

> "Applicant contends that Nelson et al. does not disclose spatially localizing a region in a biological tissue and the 2D image produced by Nelson et al. does not allow for spatial localization of a lesion. However, the applicant's interpretation of the term "spatially" to mean identification in space, more specifically three-dimensions is incorrect. The Examiner's takes the position on space to mean any of a linear distance (one-dimensional), an area (two-dimensional), and volume (three-dimensional) as evidenced by the definition of "space" by Dictionary.com. Furthermore, applicant's interpretation that Nelson et al. does not allow for spatial localization, i.e. three- dimensional location, is incorrect. The Examiner directs the applicant to the passage of Nelson et al. (col. 8, In. 18-20) which cites "two dimensional images may be obtained simultaneously, thereby providing a three dimensional image of the object". Therefore, Nelson et al. discloses a system capable of locating lesions in three dimensions. Furthermore, applicant has amended the claims to clarify "the result of a three- dimensional location of the transformed lead fields that best reproduces the frequency-dependent signal portions as a three-dimensional location of the region to be localized" (page 11, lines 16-18 of applicant's response). However, the three- dimensional location is of the lead fields as stated in applicant's response and recited in the claims. The Examiner directs the applicant to

> the passage of Scholz (abstract, line 4) which teaches determining a three-dimensional position from the lead fields as relied upon in the above rejection."

And in the Final Office Action dated 8/15/08:

> "Applicant contends that Nelson et al. does not disclose spatially localizing a region in a biological tissue. However, the Examiner respectfully disagrees with the applicant. Regarding the Examiner's interpretation of spatially localizing, the Examiner directs applicant to the response in the previous Office Action. As stated in the previous Office Action, the article of Scholz is relied upon for three-dimensional localization of lesions. Furthermore, the Examiner notes that applicant's arguments are directed to a recitation in the preamble which is generally given very little patentable weight."

Applicant argued Nelson et al. does not teach "emitting a three-dimensional location of the transformed lead fields". However, the Examiner respectfully disagreed with the applicant. The Examiner has relied upon the teachings of Scholz to teach emitting a three dimensional location (abstract, line 4) of the transformed lead fields that best reproduces the frequency-independent signal portions as a three dimensional location (abstract, line 4) of the region to be localized (section C). Section C of Scholz teaches localization of lesions in which the Examiner interprets as the region to be localized which best reproduces the frequency-independent signal portions.

Applicant argued Nelson et al. does not make any use of fluorescence. However, the Examiner respectfully disagreed with the applicant. Nelson et al. discloses fluorescence at multiple instances throughout the disclosure. For example, Nelson et al. discloses "if the tissue volume of interest contains contrast-enhancing materials or materials which can be detected through emission fluorescence or Raman

scattering or Doppler effects, then the use of multiple collimated angled beams my improve localization capabilities" (col. 9, line 65 to col. 10, line 6) and "the use of multiple angled beams and (if appropriate) compression plates can enhance the capability of an imaging system to localize the presence of contrast-enhancing materials or materials which can be detected using emission fluorescence (including tissue-dependent fluorescence lifetimes), Raman scattering techniques, or Doppler techniques, in addition to detecting any other measurable effect such materials might have on the optical beams" (col. 24, lines 29-36). Therefore, the Examiner interprets Nelson et al. to disclose and makes use of fluorescence.

Applicant's arguments with respect to Nelson et al. not providing information as to how three-dimensional image is intended to be generated is not understood. The Examiner notes that the claimed subject matter does not include imaging. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argued with respect to the motivation to combine the prior art references. However, the Examiner respectfully disagreed with the applicant. The suggestion to combine the references can be found in both Nelson et al. (column 7, lines 21-27) and Scholz (abstract, lines 1-2). Nelson et al. discloses a dual modality system (optical and ultrasound; col. 20, lines 3-7) in which the use of a second modality (col. 20, lines 3-7) aids in the identification of static and dynamic structures and in the identification of material composition of the structures (col. 20, line 65 to col. 21, line 1).

Nelson et al. suggests that electromagnetic properties of various normal and diseased breast tissues exhibit wavelength dependence and examining the effects of tissue on other electromagnetic parameters may aid in distinguishing between various types of tissues (column 7, lines 21-27). Therefore, the Examiner interprets that Nelson et al. teaches the use of a secondary modality provides aid in the identification of diseased tissue and that suggests that exploring other electromagnetic properties (i.e. electric fields) may also aid in identification of diseased tissue. The publication of Scholz teaches a method of localizing lesions by electric fields. Scholz suggests the method taught can improve breast cancer diagnosis (abstract, lines 1-2). The Examiner notes that the claim recites "comparing the input values processed from the frequency-independent signal portions with the transformed lead fields". The Examiner interprets the claim, in its broadest reasonable interpretation, to only require the step of comparing between the two sets of data (one from the detected response signals and the other from the lead fields). Therefore, the Examiner takes the position that it is obvious to one of ordinary skill in the art to compare the data as taught by both Nelson et al. and Scholz. Both Nelson et al. and Scholz teach methods for the localization of lesions and the comparison of data between the two methods would enhance the accuracy of the localization of the lesions.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Peter Luong/

Examiner, Art Unit 3737

Conferees:
/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

/Tom Hughes/
TQAS, TC 3700